JAN 1 8 2002 K012293

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name:	Topical Hemostat
Product Trade Name:	Duett™ Flowable Hemostat
Classification Name:	Unclassified Product Code, KMF
Manufacturer:	Vascular Solutions, Inc. 2495 Xenium Lane North Minneapolis, Minnesota 55441
Establishment Registration:	2134812
Contact:	Deborah Jensen V. P., Regulatory Affairs, Clinical Affairs, and Quality Systems (763) 656-4349 phone (763) 656-4252 fax
Performance Standards:	No performance standards have been developed under section 514 for this device.

Device Description:
The Duett Flowable Hemostat is comprised of a three-part procoagulant mixture consisting of collagen, thrombin and a buffered diluent. The Duett Flowable Hemostat achieves its principal intended action (hemostasis) by creating a physical barrier to blood flow and establishes an environment in which a natural blood clot can build and form a physical barrier to bleeding. The surface properties of the suspended collagen facilitate hemostasis reactions by triggering platelet adhesion and aggregation. The thrombin facilitates hemostasis by enhancing the surface-activated clotting cascade through enzymatic cleavage and conversion of fibrinogen to fibrin. The device also contains several delivery tools and mixing accessories. The device is sterilized with ethylene oxide.

Intended Use:
The Vascular Solutions Duett Flowable Hemostat is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters.

Summary of Non-Clinical Testing:
Testing conducted included assessments of the physical properties of the procoagulant (pH, viscosity, osmolarity, and deliverability), the ability of the procoagulant to achieve

its intended use (clot blood) and biocompatibility assessments. The results of this battery of tests confirmed the suitability of the Duett Flowable Hemostat for its intended use.

Summary of Clinical Testing:
No clinical evaluations of this product for this use have been conducted.

Predicate Devices:
The intended use of the Duett Flowable Hemostat is a subset of the intended use of the Syvek Patch Topical Hemostat(K984177) and is similar to that of the Hospal Tipstop Compression Dressing (K982818). These three products use slightly different technologies to control the bleeding associated with vascular access sites.

Conclusions:
The Duett Flowable Hemostat is substantially equivalent to the Syvek Patch and the Hospal Tipstop. The testing performed confirms that the Duett Flowable will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1 2003

Ms. Deborah Jensen
Vice President, Clinical
and Quality Systems
Vascular Solutions
2495 Xenium Lane North
Minneapolis, Minnesota 55441-3625

Re: K012293
Trade/Device Name: Vascular Solutions Duett Flowable Hemostat
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 30, 2001
Received: October 31, 2001

Dear Ms. Jensen:

This letter corrects our substantially equivalent letter of January 18, 2002 regarding the Duett Flowable Hemostat, which was mistakenly classified as a Class I Compression Dressing with product code MHW. As this device contains a biological component, it is unclassified with product code FRO.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your product contains the following component subject to regulation as a biologic:

Thrombin vial (5,000 units)

Our substantially equivalent determination does not apply to the biologic component of your product. For information on applicable Agency requirements for marketing this product, we suggest you contact:

Director
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, Maryland 20852-1148

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K012293

Device Name: Vascular Solutions Duett™ Flowable Hemostat

Indications for Use:

The Vascular Solutions Duett Flowable Hemostat is intended for use under the direction of a healthcare professional for the local management and control of bleeding from vascular access sites and percutaneous catheters and tubes.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012293